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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/282,679	03/31/99	FALO	L 214001-00703

003705 HM12/0214
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EXAMINER	
VANDER VEGT,F	
ART UNIT	**PAPER NUMBER**
1644	13

DATE MAILED: 02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/282,679	Falo et al
Examiner	**Group Art Unit**
F. Pierre VanderVegt	1644

☒ Responsive to communication(s) filed on *Nov 20, 2000*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-36* ~~is~~/are pending in the application.

Of the above, claim(s) *14-36* ~~is~~/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-13* ~~is~~/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *10*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application is a continuation-in-part of application S.N. 09/030,985, which claims priority to provisional application 60/039,472.

Claims 1-36 are currently pending in this application.

Election/Restriction

1. Claims 14-36 stand withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, the requirement having been traversed in Paper No. 6.

This application contains claims 14-36, drawn to inventions nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

2. Claims 1-13 remain as the subject of examination in the present Office Action.

3. In view of the amendment filed November 20, 2000, only the following rejections are maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent.

4. Claims 1-13 stand rejected under 35 U.S.C. 102(a) as being clearly anticipated by Moser et al (N on form PTO-892, of record).

It was stated previously: "The Moser et al reference teaches fusion of murine dendritic-like cells with murine mastocytoma cells (Abstract in particular). Moser et al also teaches the fusion of human dendritic-like cells with human osteosarcoma cells to form a human

dendritic/tumor hybrid cell line at a 2:1 ratio (Examples 7-9, pages 30-31 in particular). Moser et al further teaches the in vitro use of the hybridoma cells for priming autologous T cells before reinfusion of the T cells for an anti-tumor response (Abstract and claims 23-24 in particular) The prior art teaching clearly anticipates the claimed invention. Claims 7, 8, 10 and 11 are included because the instant claims are drawn to the generation of antigen-specific T cells, not to the fusion procedure, and absent any showing to the contrary by Applicant, the ratio of dendritic to tumor cells is not seen as being as being a critical factor in the ability of the hybridomas to stimulate the T cells."

Applicant's arguments filed November 20, 2000 have been fully considered but they are not persuasive.

Applicant argues that the Moser et al cannot be considered as 102 art because the reference does not teach each and every aspect of the claimed invention. Applicant argues that the sole disclosure of in vitro incubation of dendritic/tumor hybrid cells is at page 16 and that this is not an enabling disclosure. Applicant cites several pieces of case law in support of Applicant's position that the reference must teach each and every aspect of the claimed invention in order to be enabling for performing the claimed method of in vitro stimulation of T cells. The Examiner respectfully disagrees with Applicant's assessment. In *In re BROWN*, 141 USPQ 245 (CCPA 1964), cited by Applicant, the Court stated that the true test of prior art is whether the art prior art placed the invention in the possession of the public without exertion of inventive skill. In *In re HOEKSEMA*, 158 USPQ 596 (CCPA 1968), cited by Applicant, the Court stated that in order to be considered prior art commensurate with the law, the disclosure of a publication must be such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention. The Moser et al teaches that the dendritic/tumor cell hybrids can be used in vitro for the stimulation of antigen-specific T cells which can then be reinfused into a patient to effect an anti-tumor response. While Moser et al does not teach the methodology of in vitro incubation of the hybrids with T cells, the practice of co-incubating dendritic cells with T cells to stimulate the T cells was a common practice in the art at the time the invention was made. The act of incubating the dendritic/tumor cell hybrids with T cells would have been well within the purview of the artisan at the time the invention was made and would not have required the exertion of inventive skill on his/her part to successfully perform.

Applicant further argues that the dendritic/tumor cell hybrids of the Moser et al reference do not constitutively express T cell activating molecules and that their expression must be stimulated by the addition of cytokines as evidenced by page 32 of the Moser et al reference. This argument is not persuasive. First of all, there is no limitation in the instantly claimed invention that excludes the addition of cytokines or that the expression of T cell activating molecules must be constitutive. Second, as Applicant pointed out, Moser et al teaches that cytokines must be added to the cells for the expression of the T cell costimulatory molecules. However, Moser et al does teach that the cytokines must be added and that upon their addition, greater than 90% of the hybrids do express the T cell activating molecules. Therefore, Moser et al teaches the elements required to effectively use the cells for the stimulation of T cells when combined with the knowledge of the skilled artisan.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2001 365-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
February 12, 2001

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
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